MICROWAVES 7FRO IN ON BREAST TUMORS

Microwave technology produces safe and controlled deep heat to treat patients with breast cancer, prostate cancer, and other

life-threatening diseases.



■ The Celsion breast cancer treatment system (pictured above) can increase the effectiveness of breast-conserving cancer treatments, such as lumpectomy, radiation therapy, and chemotherapy.



Celsion's deep cancer treatment system (pictured above), currently being developed, will target generally inoperable tumors deep within the body. This year, the American Cancer Society estimates that 178,000 American women will be diagnosed with breast cancer and roughly 43,000 will die from the disease. Many of these lives may someday be saved by treating the tumor with heat, a technique better known as hyperthermia. But in targeting tumors deep inside the body, conventional heat treatments can create hot spots that burn the skin or surrounding healthy tissue.

Fortunately, Celsion Corporation (Columbia, MD), formerly Cheung Laboratories, has found a way to solve this problem. The company has developed a breast cancer treatment system, called Microfocus $1000^{\rm TM}$, that uses deep, focused heat to eradicate cancerous tumors—without overheating surrounding tissue. Concurrently heating and applying either radiation or chemotherapy shrinks tumors up to twice as fast as subjecting them only to conventional treatments.

Furthermore, recent preclinical tests conducted by Massachusetts General Hospital in Boston showed that heat alone can eradicate tumors effectively. This approach could eventually eliminate the need for radiation-based treatments, which can cause nausea, radiation burns, hair loss, and even secondary tumors. Later this year, Celsion plans to use this method to eradicate breast tumors in patients at several hospitals.

Cancel out radiation. Adaptive phased array (APA) software is key to the precision of Microfocus 1000. APA algorithms were initially developed by MIT Lincoln Laboratory (Lexington, MA) to locate airborne vehicles, such as cruise missiles, from BMDO space-based radar platforms. The algorithms were designed to overcome enemy jamming by removing the electronic noise from the radiation signals coming back to the radar. Since then, the same APA techniques have been applied in tumor eradication. In this application, they cancel out the radiation signals hitting healthy tissue, allowing the microwaves to be more precisely focused on the tumor.

APA technology gives doctors a new level of control in the heat treatment of tumors. "Hyperthermia systems have been around for a long time and, for the most part, they have been ineffective in reaching the tumor site with concentrated microwaves," says John Mon, Celsion's general manager. "APA technology focuses microwaves right on the tumor, killing the cancer cells more directly.

Because of its greater precision, it doesn't produce hot spots on surrounding tissue, so the patient feels no pain during or after the procedure."

Celsion is making significant progress in bringing Microfocus 1000 technology to the market. In September 1997, the company received premarket approval from the U.S. Food and Drug Administration to incorporate APA technology into its already-approved Microfocus 1000, making the device immediately available for medical use. Celsion also has obtained an exclusive license for the commercial use of MIT's APA technology. Several hospitals have successfully used Celsion's prototypes in animal models, paving the way for the treatment of human patients.

Intravenous drug delivery. In a sponsored research alliance with Duke University Medical Center in Durham, North Carolina, Celsion will use APA technology to develop a new family of heat-activated targeted drug delivery, gene therapy, and anti-angiogenesis systems. The first major emphasis of the alliance is the development of heat-sensitive lipid-based microcarriers, which encapsulate drugs for intravenous delivery. Upon reaching the tumor where the focused heat is applied, the microcarrier is designed to undergo a physical change that leads to a release of the entire encapsulated drug content within a few minutes. This approach concentrates the toxic effects of the drug at the site by 50 times that of current liposome therapies, with minimal side effects.

Celsion is also developing APA-based devices for treating prostate cancer and other life-threatening diseases. The APA prostate cancer treatment system will increase the effectiveness of radiation therapy by about a factor of two without any added side effects. Preclinical testing is currently being conducted in Celsion's laboratory with a prototype. This year, Celsion will ship the prototype to the University of California at San Francisco where preclinical studies using animals without tumors will be conducted.

A deep cancer treatment system also uses the focused-heating APA method, safely eradicating tumors far inside the body without harming surrounding tissue. The system is designed to target tumors in the liver, rectum, cervix, pancreas, lung, and other areas deep within the torso. The prototype, which is currently being developed, will be used in clinical trials at both Duke University Medical Center and Northwestern Memorial Hospital in Chicago, Illinois.

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What Does It Mean to You? Celsion's new technology offers more accurate delivery of thermal therapy for eradicating cancerous breast tumors, helping to widen the range of treatment choices for women with these disorders.

What Does It Mean to Our Nation? Celsion's Microfocus

1000 can be used as

part of the thousands of breast-conserving surgeries that are performed each year, reducing the complications and risks associated with these procedures.

